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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,087	06/21/2000	Anthony J. Polverino	00,450	6624

20306 7590 01/28/2005

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/599,087	LUETHY ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed September 27, 2004 is acknowledged and has been entered. Claims 3 and 5-8 have been amended.

2. Claims 1-8 are pending in the application.

3. Claims 1, 2, and claims 3-8, insofar as the claims are drawn to an isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, are currently under continued prosecution.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The following Office action contains NEW GROUNDS of rejection necessitated by amendment.

Grounds of Objection and Rejection Withdrawn

6. Unless specifically reiterated below, the amendment filed September 27, 2004 has obviated the grounds of objection and rejection set forth in the previous Office action mailed March 26, 2004.

Grounds of Objection and Rejection Maintained

Claim Objections

7. The objection to claims 3-8, because the claims are drawn to the subject matter of non-elected inventions, is maintained.

At pages 5 and 6 of the amendment filed September 27, 2004, Applicant has asserted that the claims, as amended, no longer encompass the subject matter of non-elected inventions. However, to the contrary, claims 3-8 still encompass an isolated

nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide that does not comprise the amino acid sequence of SEQ ID NO: 5.

Appropriate correction is required.

Claim Rejections

8. The rejection of claims 1-5 and 7 under 35 U.S.C. 102(b), as being anticipated by Hillier et al. (GenBank EST Database Accession No. AA422178, 1997), as evidenced by a USPTO database search using SEQ ID NO: 5 as a query (see USPTO Search Report US-09-599-087-5.rst, result 2), is maintained.

Applicant has traversed this ground of rejection arguing the prior art does not anticipate the claimed invention. Applicant' arguments are set forth at pages 6-8 of the amendment filed September 27, 2004.

Applicant's arguments have been carefully considered, but not found persuasive for the following reasons:

Hillier et al. teaches the polynucleotide sequence of an isolated nucleic acid molecule encoding an amino acid sequence that is 100% identical to the amino acid sequence set forth in SEQ ID NO: 5 over the region spanning from the amino acid at position 1 to the amino acid at position 76. According to the annotation of GENBANK Accession No. AA422178, the polynucleotide sequence of the complementary DNA (cDNA) molecule of Hillier et al. is contained in a modified vector originally designated pT7T3D. The recombinant vector comprising the polynucleotide sequence of the cDNA molecule was cloned in a host prokaryotic cell designated DH10B.

Contrary to Applicant's arguments, the nucleic acid molecule of Hillier et al. comprises a polynucleotide sequence that is complementary to the nucleotide sequence of SEQ ID NO: 4, since the nucleic acid molecule of Hillier et al. comprises the polynucleotide sequence set forth between nucleotide residues 1 and 60, which is complementary to the polynucleotide sequence of SEQ ID NO: 4. Accordingly, Hillier et al. anticipates the invention of claim 1, which in this instance is interpreted as an isolated nucleic acid molecule *comprising* a nucleotide sequence complementary to the nucleotide sequence of SEQ ID NO: 4.

Furthermore, absent a showing of any difference, the nucleic acid molecule of Hillier et al. is deemed the same as the claimed nucleic acid molecule comprising the nucleotide sequence of the DNA insert in the ATCC Deposit No. PTA-1755, which encodes a variant of the polypeptide encoded by SEQ ID NO: 4.

At page 7 of the amendment, Applicant has asserted the specification teaches, at page 84 (lines 15-19), that the ATTC deposit having the accession number PTA-1755 comprises a cDNA encoding a human Secs-1 polypeptide, not an allelic variant or splice variant of the nucleotide sequence of SEQ ID NO: 4. In reply, it is duly noted that the disclosure at page 84 to which Applicant has referred does not address whether the deposited material comprises a cDNA molecule encoding a human Secs-1 polypeptide that is an allelic variant or splice variant of SEQ ID NO: 4. However, at page 2 (lines 26-29), the specification teaches:

> The invention also provides for an isolated nucleic acid molecule comprising [...] a nucleotide sequence encoding an allelic variant or splice variant of the nucleotide sequence as set forth in SEQ ID NO: 1 or SEQ ID NO: 4, the nucleotide sequence of the DNA insert in ATCC Deposit Nos. PTA-1753 or PTA- 1755.

Contrary to Applicant's remarks, this disclosure appears to teach that the deposited material comprises a nucleic acid molecule comprising a nucleotide sequence encoding an allelic variant or splice variant of the polypeptide encoded by SEQ ID NO: 4.

Regarding claim 2, the nucleic acid molecule of Hillier et al. comprises, for example, the region of the polynucleotide sequence of SEQ ID NO: 4 spanning nucleotide residues 29 to 130, which encodes amino acids 1-34 of SEQ ID NO: 5. Although Applicant has argued that, because the prior art does not teach a nucleic acid molecule comprising SEQ ID NO: 4, the prior art cannot be said to teach a nucleic acid molecule comprising a region of the nucleotide sequence of SEQ ID NO: 4, the nucleic acid molecule of the prior art cannot be distinguished from the claimed nucleic acid molecule. Because the nucleic acid molecule is indistinguishable from the claimed nucleic acid molecule, absent a showing of any difference, the prior art is deemed anticipatory.

However, after reconsideration of the rejection of claim 2, because the prior art does not disclose the open-reading frame of the disclosed polynucleotide sequence, it cannot be said that the region will unquestionably encode a polypeptide of at least 25 amino acids, but not more than 80 amino acids, which upon injection into an animal would produce an antibody that binds to the polypeptide of SEQ ID NO: 5. If an alternate reading frame not encoding the amino acid sequence of SEQ ID NO: 5 is translated, the polypeptide encoded by the disclosed nucleic acid molecule would not be expected to be capable of eliciting the production of an antibody that binds the polypeptide of SEQ ID NO: 5.

As for claim 3, the nucleic acid molecule of Hillier et al. comprises a polynucleotide sequence that is complementary to the nucleotide sequence of SEQ ID NO: 4 encoding the polypeptide of SEQ ID NO: 5. For example, the nucleic acid molecule of Hillier et al. comprises the polynucleotide sequence set forth between nucleotide residues 1 and 60, which is complementary to the polynucleotide sequence of SEQ ID NO: 4, or which is complementary to a nucleotide sequence encoding the polypeptide of SEQ ID NO: 5. Therefore, Hillier et al. anticipates the invention of claim 3.

9. The rejection of claims 1-5 and 7 under 35 U.S.C. 102(b) as being anticipated by Database GENBANK Accession No. AA283751, as evidenced by the declaration under 37 CFR § 1.131 by Anthony J. Polverino and Roland Luethy filed September 25, 2002 as part of Paper No. 18, Hillier et al. (*Genome Research* **6**: 807-828, 1996), Exhibit A (a printout of Internet accessible information regarding GENBANK Accession No. AA283751), and Exhibit B (an email communication from Christa Prange of the IMAGE Consortium dated May 12, 2003 in reply to the Examiner's query made May 7, 2003), is maintained.

Applicant has traversed this ground of rejection. Applicant's arguments are set forth in the amendment filed September 27, 2004 at pages 8 and 9.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Applicant has argued that the actual sequence of the nucleic acid molecule disclosed by the prior art was not publicly accessible; while the sequence of the nucleic acid molecule may have been incorrectly reported in the database, the claims are drawn to a nucleic acid molecule, as opposed to a sequence, and the nucleic acid molecule disclosed by the prior art is deemed the same as the claimed nucleic acid molecule for reasons already of record.

Applicant has referred to the Court's decision in deciding *In re Hall*; the case law to which Applicant has referred indicates that the prior art must be accessible to the public, so that one could make the claimed invention without further research or experimentation. As established by the previous Office action, the nucleic acid molecule is, and has been publicly accessible since April or May of 1997. As evidenced by the declaration under 37 CFR § 1.131 by Anthony J. Polverino and Roland Luethy filed September 25, 2002, the nucleic acid molecule comprises the sequence set forth in the instant application as SEQ ID NO: 4. Having procured the publicly accessible clone from the IMAGE consortium, as did Applicant, the claimed invention could be made without further research or experimentation, as the cloned cDNA molecule is the claimed invention.

10. The rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Hillier et al. (GenBank EST Database Accession No. AA422178, 1997), as evidenced by a USPTO database search using SEQ ID NO: 5 as a query (see USPTO Search Report US-09-599-087-5.rst, result 2), in view of Bendig (*Genet Eng* **7**: 91-127, 1988) and Niwa et al. (*Gene* **108**: 193-199, 1991), is maintained.

Applicant has traversed this ground of rejection arguing the prior art does not anticipate the claimed invention. Applicant' arguments are set forth at pages 9 and 10 of the Amendment filed September 27, 2004.

Applicant's arguments have been carefully considered but not found persuasive for the same reasons Applicant's arguments traversing the corresponding rejection under 35 USC § 102 were not.

11. The rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Database GENBANK Accession No. AA283751, as evidenced by the declaration under 37 CFR § 1.131 by Anthony J. Polverino and Roland Luethy filed September 25, 2002 as part of Paper No. 18, Hillier et al. (*Genome Research* **6**: 807-828, 1996), Exhibit A (a printout of Internet accessible information regarding GENBANK Accession No. AA283751), and Exhibit B (an email communication from Christa Prange of the IMAGE Consortium dated May 12, 2003 in reply to the Examiner's query made May 7, 2003) in view of Bendig (*Genet Eng* **7**: 91-127, 1988) and Niwa et al. (*Gene* **108**: 193-199, 1991), is maintained.

Applicant has traversed this ground of rejection arguing the prior art does not anticipate the claimed invention. Applicant' arguments are set forth at pages 9 and 10 of the Amendment filed September 27, 2004.

Applicant's arguments have been carefully considered but not found persuasive for the same reasons Applicant's arguments traversing the corresponding rejection under 35 USC § 102 were not.

New Ground of Rejection

12. Claims 1 and 4-8 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 1 and 4-8 fail to correspond in scope with that which Applicant regards as the invention can be found in the reply filed September 27, 2004. In that paper, Applicant has stated, "the sequences cannot anticipate claim 1, because the claim does not encompass nucleic acid molecules comprising a nucleic acid sequence that is complementary to a *portion* of SEQ ID NO: 4" (underlining and italics in original). This statement indicates that the invention is different from what is defined in the claims because claim 1 presently recites, "[a]n isolated nucleic acid molecule comprising a nucleotide sequence [...] that is complementary to the nucleotide sequence of any of [a nucleic acid molecule comprising a nucleotide sequence as set forth in SEQ ID NO: 4, a nucleic acid molecule comprising a nucleotide sequence of the DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755, or a nucleic acid molecule

comprising a nucleotide sequence encoding a polypeptide as set forth in SEQ ID NO: 5]". Claim 1 is not limited to a nucleic acid molecule comprising a nucleotide sequence that is the full complement of the nucleotide sequence of any of the aforementioned nucleic acid molecules. Accordingly, contrary to Applicant's remarks, the claims encompass a nucleic acid molecule comprising a nucleotide sequence that is complementary, partially or fully, to the nucleotide sequence of any of the aforementioned nucleic acid molecules.

Conclusion

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
January 25, 2005

LARRY R. HELMS, PH.D
PRIMARY EXAMINER

LARRY R. HELMS, PH.D
PRIMARY EXAMINER